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Research Article

A STUDY OF PHYTOPHARMACOGNOSTIC AND CLINICAL EFFICACY OF *PALASHA BEEJA* (*BUTEA MONOSPERMA* LAN-KUTZE) IN *PRAMEHA* W.S.R. TO DIABETES MELLITUS-II

Anuj Jain[1]*, Drakshayani N. Benni[2], Ashvini S. M[3]

*[1]Post Graduate Scholar, [2]Professor, [3]Associate Professor, Dept. of Dravya Guna, Sri Shivayogeeshwar Rural Ayurvedic Medical College and Hospital, Inchal, Savadatti, Belagavi, Karnataka, India.

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ABSTRACT

Prameha Vyadhi, known as Type 2 Diabetes Mellitus in contemporary science, is classified as one of the *Ashtamahagadas* due to its chronic nature and involvement of *Tridoshas* and *Dasha Dushya*. It is considered *Kruchrasadya* or *Yapya*, emphasizing the need for maintaining proper control and management to avoid complications. *Ayaskriti*, categorized under *Arishta Kalpana*, possesses *Katu-Tikta-Kashaya Rasa* and *Laghu, Ruksha, Teekshna Guna*, which provide *Deepana-Pachana* properties and aid in *Kapha-Kleda-Medo Upashoshana*, essential in the treatment of *Prameha*. This study evaluates the efficacy of *Palasha Beeja Ghana Vati* as *Abhyantara Shamana Chikitsa* in the management of *Prameha*. **Aims and Objectives:** 1. To assess the efficacy of *Palasha Beeja Ghana Vati* (*Butea monosperma* Lam.-Kuntze) in *Prameha*, with special reference to Type 2 Diabetes Mellitus. 2. To conduct a preliminary phytochemical evaluation of *Palasha Beeja.* 3. To analyze the pharmacognostic properties of *Palasha Beeja Ghana Vati* in *Prameha Vyadhi*. **Materials and Methodology:** This is a clinical study with pre-test & post-test design. A total of 40 patients diagnosed with *Prameha* were selected, irrespective of sex, religion, occupation, or economic status. **Intervention: Trail Group:** Patient were administered with *Palasha Beeja Ghana Vati*- 500mg twice a day, before food*.* **Observations and Results:** The effect of the treatment was assessed on before the treatment and after the treatment by applying Wilcoxon's rank sum test within the group respectively. It was Seen the treatment with *Palasha Beeja Ghana Vati* was effective in treating *Prameha Vyadhi.* **Discussions and Conclusion:** The study can be concluded from the study that in the management of *Prameha,* the *Shamana Chikitsa* with *Palasha Beeja Ghana Vati* (*Butea monosperma* Lan-Kutze) was effective and plays an important role in *Prameha*.

INTRODUCTION

The modern lifestyle, characterized by sedentary habits, unhealthy dietary patterns, and environmental factors, has led to a significant rise in non-communicable diseases like Type 2 Diabetes Mellitus (T2DM). T2DM, a metabolic disorder resulting from insulin resistance or inadequate insulin secretion, is marked by hyperglycemia and disturbances in carbohydrate, protein, and fat metabolism. If unmanaged, it predisposes individuals to severe complications such as cardiovascular disease, retinopathy, nephropathy, neuropathy, and diabetic foot.

Globally, T2DM poses a growing public health challenge. In 2021, an estimated 537 million individuals were affected, representing about 6.8% of the global population. This figure is projected to surge to 643 million by 2030[1]. While conventional treatments, including insulin therapy and oral hypoglycemic agents, provide glycemic control, their prolonged use often demands escalating doses and carries risks of adverse effects such as hypoglycemia, gastrointestinal discomfort, and organ dysfunction[2].

Given the chronic nature of T2DM, there is an increasing demand for alternative treatments with fewer side effects. Ayurveda, with its holistic approach and reliance on herbal formulations, presents a

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promising therapeutic avenue. Ayurvedic texts extensively discuss *Prameha*, which parallels T2DM, and highlight herbal remedies like *Palasha Beeja* (Butea monosperma). Economical and widely available, this herbal intervention offers a sustainable and non-synthetic alternative for managing T2DM.

This study evaluates the efficacy of *Palasha Beeja Ghana Vati* as a *Shamana Aushadhi* in T2DM management, focusing on its impact over 30 days of treatment followed by a 15-day follow-up, with promising outcomes observed in glycemic control and symptom relief.

Methodology

This clinical study was conducted to evaluate the therapeutic efficacy of *Palasha Beeja Ghana Vati* as *Shamana Chikitsa* for *Prameha*. The phyto-pharmacological and internal properties of *Palasha Beeja* were extensively analyzed through laboratory studies. *Palasha Beeja* is referenced in Ayurvedic texts for its effectiveness in managing *Prameha Vyadhi*, attributed to its *Rasa, Guna, Veerya*, and *Vipaka*. The study was meticulously designed, drawing from classical Ayurvedic literature and prior research findings, to validate its role in the management of *Prameha*.

Hypothesis

- **Null Hypothesis: H_0-** There is NO Significant Effect of *Palasha Beeja Ghana Vati* (*Butea monosperma* Lan-Kutze) in *Prameha* W.S.R. to Diabetes Mellitus-II.
- **Alternate Hypothesis: H_1-** There is Significant Effect of *Palasha Beeja Ghana Vati* (*Butea monosperma* Lan-Kutze) in *Prameha* W.S.R. to Diabetes Mellitus-II.

Source of Data

1. **Literary source:** Ayurvedic texts, contemporary textbooks, journals, e-books, prior research materials, and imprint resources from the library pertaining to the disease, procedure, and drugs were comprehensively reviewed and documented for this study.
2. **Sample source:** 40 patients exhibiting symptoms of *Prameha*, who met the inclusion criteria, were selected for the study using random sampling techniques. These patients were approached from the Out-patient and In-patient departments of *Dravyaguna* and other departments at Shri Shivayogeeshwar Rural Ayurvedic Medical College & Hospital, Inchal.
3. **Disease Review- Ayurvedic Perspective:** *Prameha* is a *Santarpanajanya Vyadhi* caused by vitiation of *Tridosha* and *Dushyas*[3] like *Meda, Rakta*, and *Kleda*. It is extensively discussed in texts such as *Charaka Samhita* and *Sushruta Samhita*. Factors increasing *Kapha, Medo*, and *Mansa* in *Mutrashaya* lead to *Madhumeha*. *Prameha* is classified into *Kaphaja, Pittaja*, and *Vataja*, further divided into 20 types[4]. Untreated *Prameha* can progress to *Madhumeha*[5]. The use of *Palasha Beeja* in *Madhumeha* is highlighted in texts like *Bhavprakash Samhita*[6], *Sushruta Samhita*[7], *Ashtanga Hridaya*[8], *Kaiyadeva Nighantu*[9], and *Vaidya Sahachar*[10].
4. **Disease Review- Modern Perspective:** Type 2 diabetes involves insulin resistance in the liver and muscles, combined with impaired pancreatic beta-cell function. This leads to excessive glucose production by the liver and reduced glucose utilization in muscles. Early stages show a moderate reduction in pancreatic islet mass[11].
5. **Drug Source:** The required drug for preparing *Palasha Beeja Ghana Vati* (*Butea monosperma* Lam.-Kuntze) was collected from wild regions near Shivpuri, Madhya Pradesh, and authenticated by the *Dravya Guna* Department. *Palasha Beeja Ghana Vati* was prepared at the pharmacy of Shri Shivayogeeshwar Rural *Ayurvedic* Medical College & Hospital, Inchal.

   Phytopharmacognostic study, including macroscopic study, organoleptic characters, and physiochemical analysis (moisture content, ash value, acid-soluble/insoluble ash, water-soluble/ insoluble ash, pH, and specific gravity), was conducted at K.L.E Central Research Laboratory, Belagavi.
6. **Drug review:** *Palasha*- Butea monosperma, belonging to the family Leguminosae, is known by various synonyms such as *Kinshuka, Raktapushpaka, Ksharashreshtha*, *Brahmavruksha, Samidvar, Parna, Yagyiya*, and *Vatapoth*. It is an erect tree that grows up to 50 feet in height, with a crooked trunk. The leaves are compound and trifoliate, with petioles measuring 10–15cm in length. The flowers are long-pedicelled, with calyces that are densely velvety on the outside and dark olive green in colour. The seeds are kidney-shaped, measuring 3–3.5cm in length, 2–2.5cm in width, and up to 2 mm in thickness. Their surface is leathery, glossy, veined, wrinkled, and deep reddish-brown in color[12].

   The plant exhibits properties such as *Katu, Tikta*, and *Kashaya* in *Rasa*, with *Guna* being *Laghu* and *Ruksha*. Its *Veerya* is *Ushna*, and *Vipaka* is *Katu*, while it is *Kaphavatashamak* in nature. It is described as having multiple actions, including *Madhumehahar*, *Arshoghna, Krumighna, Gulmahar, Kushthahar*, and *Udara Roganashak*. *Butea*

monosperma is widely distributed across India, Burma, and Ceylon, with significant presence in Madhya Pradesh, Uttar Pradesh, and Jharkhand.

7. **IEC:** The study was commenced following approval from the institutional ethical committee, with IEC Ref No: SSRAMC/IECC/2022/.
8. **CTRI Registration:** he CTRI registration was successfully completed with the CTRI Reference No.: REF/2024/08/090701 and CTRI No: CTRI/2024/08/073141.

Study design

- Study Type: Interventional
- Allocation: Randomized
- Endpoint Classification: Efficacy study
- Intervention Model: Single group assignment
- Primary Purpose: Treatment
- Masking: Open label
- Treatment duration: 30 days
- Follow-up duration: 15 days
- Total duration of study: 45 days

Diagnostic criteria

- Diagnosis will be made on basis of classical Signs and Symptoms of *Prameha*.
- *Lakshanas* as mentioned in Ayurvedic text are – *Prabhutaavila Mutrata, Trushna, Kara-Padyo Suptata Daho, Mukha-Talu-Kantha Shosha, Vistram Sharir Gadha, Shatapad Pipilikabhishcha Sharira Mutrabhisaranam, Madhuryamasyasa, Dantadiham Mala Sanchayam, Jatili Bhava Kesheshu.*

Inclusion criteria

- Subjects of either gender presenting with the symptoms of *Prameha*.
- Patients aged between 25 to 60 years, of either gender.
- Fasting Blood Sugar (FBS) levels of 126 mg/dl or higher, and Post Prandial Blood Sugar (PPBS) levels of 200mg/dl or higher.
- Patients willing to participate in the research trial and sign the informed consent form.

Exclusion criteria

- Patients outside the age group of 25 to 60 years and pregnant women.
- Patients with Fasting Blood Sugar (FBS) levels above 300mg/dl and Post Prandial Blood Sugar (PPBS) levels above 400mg/dl.
- Patients with known major illnesses such as hypertension, heart disease, thyroid disorders, severe systemic disorders, etc.
- Patients currently receiving any other treatments or medications, including steroids, NSAIDs, AKT, ART, etc.
- Known cases of Type 1 Diabetes Mellitus (DM).

Investigations

- Fasting Blood Sugar (FBS)
- Post Prandial Blood Sugar (PPBS)
- Fasting Urine Sugar (FUS)
- Post Prandial Urine Sugar (PPUS)
- Complete Blood Count (CBC) – Only if required

Interventions: 40 patients who met the Inclusion Criteria were selected and administered the treatment.

Treatment Protocol: The treatment protocol for the study involved the administration of *Palasha Beeja Ghana Vati* (*Butea monosperma* Lan-Kutze). The drug was administered orally in a dose of 500mg. The recommended *Anupana* for this treatment was *Koshna Jala* (lukewarm water). The treatment was administered twice daily, with the first dose taken in the morning at 9 am and the second dose in the evening at 7 pm. This regimen was followed for the duration of the study.

***Shamana Chikitsa*: Trail Group**

Poorva Karma

Preparation of Medicine

Collection of Drugs

- Collected *Palasha Beeja* was dried in the shade.
- Seeds were soaked in water overnight.
- The external layer of the seeds was removed the following day.
- Seeds were then made into small pieces.

***Kalpa* Preparation**

- 5kg of *Palasha Beeja* (1 part) was mixed with 80 liters of water (16 parts), and the mixture was boiled until the *Kashaya* was reduced to 20 liters ($1/4^{th}$ of the original quantity).
- The entire content was filtered using a cloth.
- The *Palasha Kashaya* was boiled further and reduced to a semisolid consistency.
- The final drug was made into pills of 500mg each

Preparation of the Patient

- Conducted pre-assessment and clinical examination of the patient to evaluate their condition.
- Obtained informed consent from the patient for participation in the research trial.
- Performed necessary laboratory investigations to establish baseline health data.

Pradhana Karma

- Administered *Palasha Beeja Ghana Vati* orally.
- Dose: 500mg with *Koshna Jala*.
- Timing: Morning at 9 AM and Evening at 7 PM.
- Duration: Administered for 30 days.

Pashchat Karma

- Observed the patient's condition.
- Advised *Pathya Ahara* and *Vihara* for the patients.

Chart for Grading of Subjective Criteria

Table 1: Grading of Subjective Criteria for Trail Group

S.No.	Criteria	Assessment Grading
1.	*Prabhuta Avila Mutrata*	0 = 3 – 5 frequency with 1.6 – 2 liters/clear urine 1 = 6 – 8 frequency with 2.1 – 2.5 liters/faintly cloudy or hazy with slight turbidity 2 = 9 – 11 frequency with 2.6 – 3 liters/turbidity clearly present but newsprint can be read 3 = >12 frequency with >3.1 liters/newsprint can't be visualized
2.	*Trushna*	0 = Intake of water 5 – 7 times with quantity up to 1.6 – 2 liters 1 = Intake of water 8 – 10 times with quantity up to 2.1 – 2.5 liters 2 = Intake of water 11 – 13 times with quantity up to 2.6 – 3 liters 3 = Intake of water >14 times with quantity up to >3.1 liters
3.	*Kara-Padayo Suptata Daho*	0 = No *Daha/Suptata* 1 = *Kara-Pada Daha/Suptata* in continuous and occasional 2 = *Kara-Pada Daha/Suptata* Moderate and Daily activity is not Hampered 3 = *Kara-Pada Daha/Suptata* Continuous, Severe and Unbearable
4.	*Mukha-Talu-Kantha Shosha*	0 = Normal i.e., No *Shosha* 1 = Feeling of Thirst Off and On. 2 = Feeling of Thirst, can only be Managed by a Glass of Water 3 = Feeling of Thirst Severe, can be managed by drinking sufficient amount of water
5.	*Madhuryam asyata*	0 = No Sweetness in Mouth 1 = Mild Sweetness in Mouth 2 = Moderate Sweetness in Mouth 3 = Severe Sweetness in Mouth

Chart for Grading of Objective Criteria

Table 2: Grading of Objective Criteria for Trail Group

S.No.	Criteria	Assessment Grading
1.	Fasting Blood Sugar	0 = <126 1 = 126 – 170 2 = 171 – 215 3 = 216 – 260 4 = 261 – 300
2.	Post Prandial Blood Sugar	0 = <200 1 = 201 – 250 2 = 251 – 300 3 = 301 – 350 4 = 351 – 400
3.	Fasting Urine Sugar	0 = Absent or Trace 1 = **+ (1+)** 2 = **++ (2+)** 3 = **+++ (3+)** 4 = **++++ (4+)**
4.	Post Prandial Urine Sugar	0 = Absent or Trace 1 = **+ (1+)** 2 = **++ (2+)** 3 = **+++ (3+)** 4 = **++++ (4+)**

OBSERVATIONS

Chronicity

Table 3: Observations on Chronicity of Patients of Trail Group

S.No.	Chronicity In Years	No of patients and percentage	
		Trail Group	Total %
1	0 – 2 Years	12	30%
2	2.1 – 4 Years	9	22.5%
3	4.1 – 6 Years	7	17.5%
4	6.1 – 8 Years	8	20%
5	Above 8 Years	4	10%

Koshta

Table 4: Observations on *Koshta* of Patients Trail Group

S.No.	*Koshta*	No of patients and percentage	
		Trail Group	Total %
1.	*Krura Koshta*	8	20%
2.	*Mrudu Koshta*	16	40%
3.	*Madhyama Koshta*	16	40%

Agni

Table 5: Observations on *Agni* of Patients Trail Group

S.No.	*Agni*	No of patients and percentage	
		Trail Group	Total %
1.	*Mandagni*	9	22.5%
2.	*Vishamagni*	18	45%
3.	*Teekshnagni*	13	32.5%

Prakruthi

Table 6: Observations on *Prakruti* of Patients Trail Groups

S.No.	*Prakruti*	No of patients and percentage	
		Trail Group	Total %
1.	*Vata-Pitta Prakruti*	6	15%
2.	*Kapha-Vata Prakruti*	26	65%
3.	*Kapha-Pitta Prakruti*	8	20%

Nidra

Table 7: Observations on *Nidra* of Patients Trail Groups

S.No.	*Nidra*	No of patients and percentage	
		Trail Group	Total %
1.	*Diwaswapna*	24	60%
2.	*Ratrijagarana*	16	40%

Descriptive Statistics of Trail Group

Wilcoxon Signed Rank Test

Table 8: Statistics within Trail Group

S.No.	Criteria	Pt. No.	Time	Mean	Std. Dev	Min	Max	25%	50% Med	75%
Subjective Criteria										
1.	*Prabhuta Avila Mutrata*	40	BT	2.18	0.636	1	3	2.00	2.00	3.00
		40	AT	1.25	0.543	0	2	1.00	1.00	2.00
		40	AF	0.53	0.599	0	2	0.00	0.00	1.00

2.	*Trushna*	40	BT	1.88	0.757	1	3	1.00	2.00	2.00
		40	AT	1.00	0.716	0	2	0.25	1.00	1.75
		40	AF	0.28	0.452	0	1	0.00	0.00	1.00
3.	*Kara-Padayo Suptata Daho*	40	BT	1.88	0.686	1	3	1.00	2.00	2.00
		40	AT	1.10	0.672	0	2	1.00	1.00	2.00
		40	AF	0.40	0.496	0	1	0.00	0.00	1.00
4.	*Mukha-Talu-Kantha Shosha*	40	BT	2.10	0.672	1	3	2.00	2.00	3.00
		40	AT	1.33	0.572	0	2	1.00	1.00	2.00
		40	AF	0.80	0.687	0	2	0.00	1.00	1.00
5.	*Madhuryam asyata*	40	BT	1.70	0.723	1	3	1.00	2.00	2.00
		40	AT	1.23	0.698	0	3	1.00	1.00	2.00
		40	AF	0.55	0.639	0	2	0.00	0.00	1.00
Objective Criteria										
6.	Fasting Blood Sugar	40	BT	3.25	0.670	2	4	3.00	3.00	4.00
		40	AT	2.07	0.694	1	3	2.00	2.00	3.00
		40	AF	1.35	0.700	0	3	1.00	1.00	2.00
7.	Post Prandial Blood Sugar	40	BT	3.00	0.784	1	4	2.25	3.00	4.00
		40	AT	1.85	0.662	1	3	1.00	2.00	2.00
		40	AF	1.30	0.648	0	2	1.00	1.00	2.00
8.	Fasting Urine Sugar	40	BT	2.90	0.744	2	4	2.00	3.00	3.00
		40	AT	1.82	0.675	1	3	1.00	2.00	2.00
		40	AF	1.35	0.700	0	3	1.00	1.00	2.00
9.	Post Prandial Urine Sugar	40	BT	2.93	0.694	2	4	2.00	3.00	3.00
		40	AT	1.85	0.533	1	3	2.00	2.00	2.00
		40	AF	1.38	0.667	0	2	1.00	2.00	2.00

Observations on Lab Reports

Macroscopic Tests

Table 9: Macroscopic Tests

S.No.	Tests	Limits	Results
1.	Part	Seed	Seed
2.	Colour	Dark Reddish Brown	Dark Reddish Brown
3.	Taste	Slightly Acid & Bitter	Slightly Acid & Bitter
4.	Odour	Faint	Faint

Physico-chemical Standard Tests

Table 10: Physico-chemical Standard Tests

S.No.	Tests	Limits	Results
1.	Loss on Drying	NA	6.937%
2.	Ash Value	Not more than 7%	5.150%
3.	Acid insoluble Ash	Not more than 0.5%	0.291%
4.	Water Soluble Ash	NA	1.108%
5.	Water Soluble Extractive	Not more than 25%	49.544%
6.	Alcohol Soluble Extractive	Not more than 9%	13.902%

Phytochemical Screening Tests

Table 11: Preliminary Phytochemical Screening Tests in following Extracts

S.No.	Tests	Water	Alcohol
1.	Tests for Carbohydrates	Positive	Positive
2.	Tests for Reducing Sugar	Positive	Negative
3.	Test for Monosaccharides	Negative	Negative
4.	Test for Pentose Sugar	Negative	Positive
5.	Test for Non reducing Sugar	Negative	Negative
6.	Test for Hexose Sugar	Negative	Negative
7.	Test for Proteins	Negative	Positive
8.	Test for Amino Acids	Positive	Positive
9.	Test for Steroids	Positive	Negative
10.	Test for Flavonoids	Positive	Positive
11.	Test for Alkaloids	Negative	Negative
12.	Test for Tannins	Negative	Negative
13.	Test for Glycosides		
a.	Cardiac Glycosides	Negative	Positive
b.	Anthraquinone Glycosides	Negative	Negative
c.	Saponin Glycosides	Positive	Positive

Total Flavonoid Content Test

Table 12: Report for Total Flavonoid Content Test

S.No.	Sample Code	Sample Name	Type of Cold Extract	Results
1.	RM/194	Palasha Seed	Water	(1.41 +/- 0.35) mg QE / gram of Extract

Total Phenolic Content Test

Table 13: Report for Total Phenolic Content Test

S.No.	Sample Code	Sample Name	Type of Cold Extract	Results
1.	RM/194	Palasha Seed	Hydro Alcoholic Extract (70%)	(9.65 +/- 0.32) mg GAE / gram of Extract

Drug Authentication Test

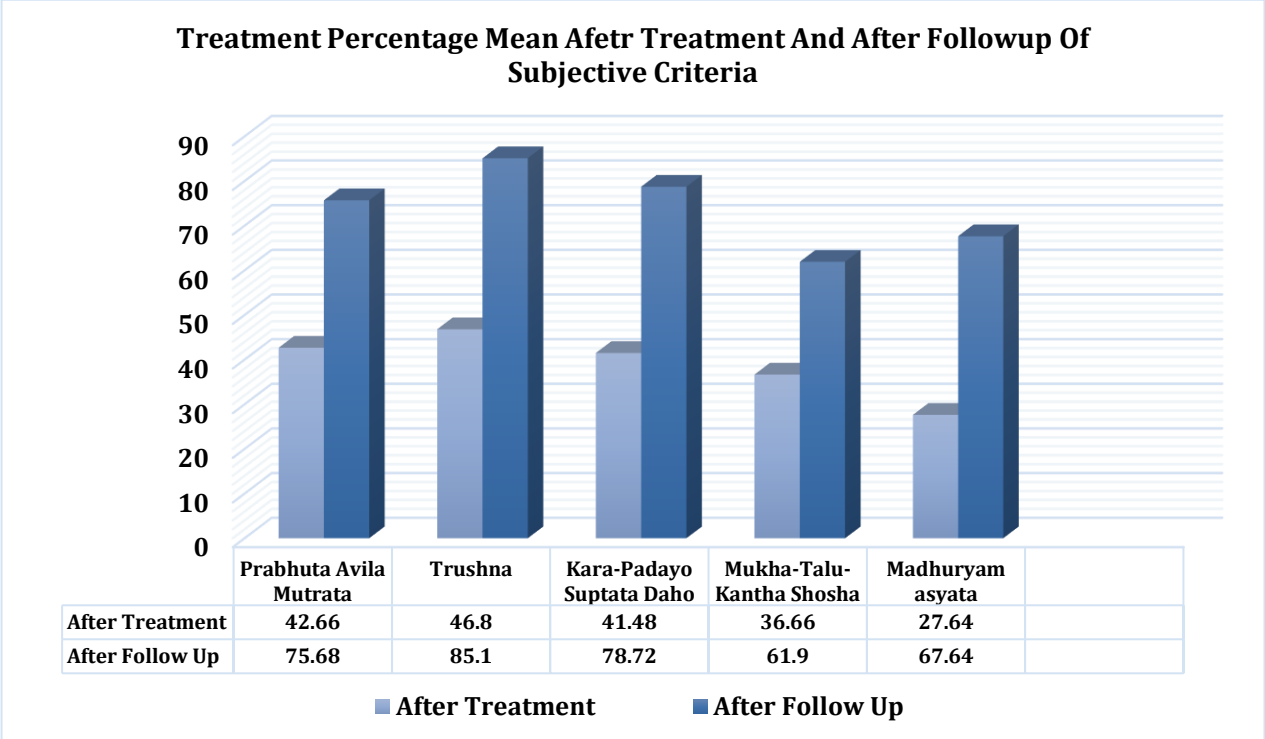
Table 14: Report for Drug Authentication Test

S.No.	CRF Code	Common Name	Scientific Name	Family	Part Authenticated
1.	CRF/Auth/443 /2024	Palasha	Butea monosperma Lan-kutze.	Leguminosae	Seed

RESULT

Table 15: Result of Treatment Percentage Mean of Subjective Criteria

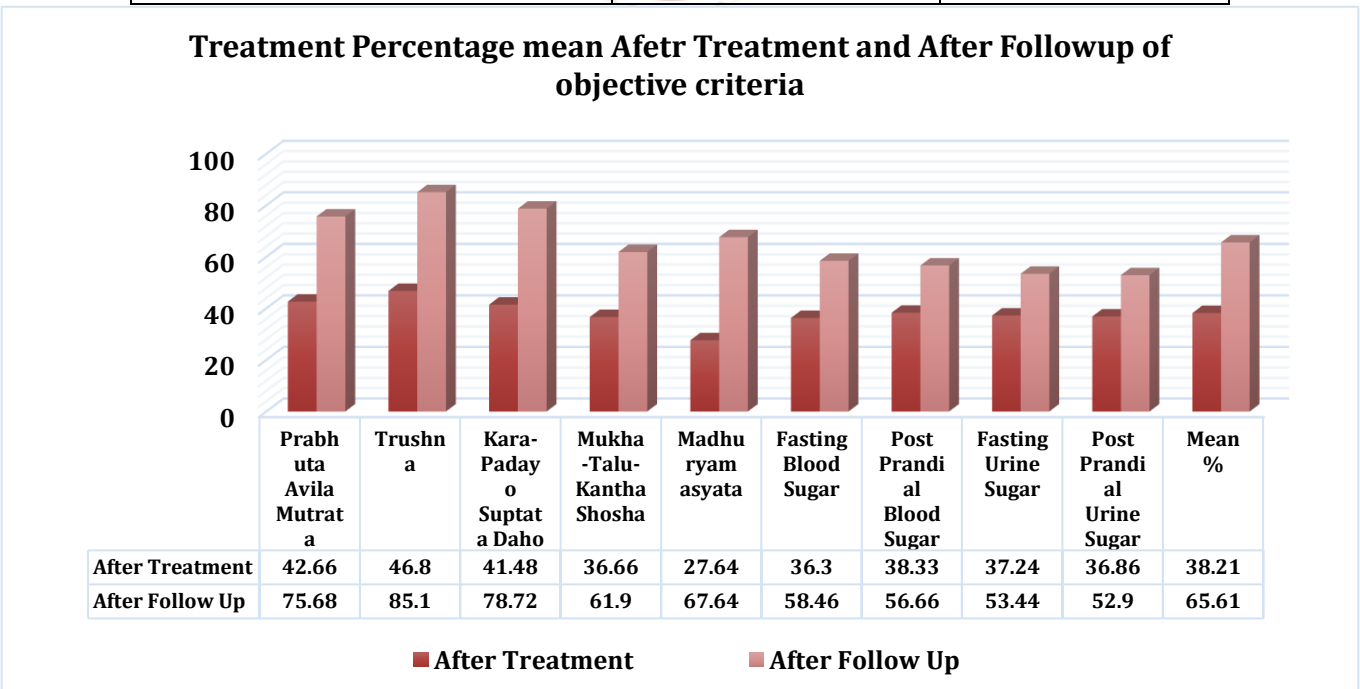
S.No.	Parameters	Mean Change Treatment %	
		After Treatment	After Follow-up
Subjective Parameters			
1.	*Prabhuta Avila Mutrata*	42.66%	75.68%
2.	*Trushna*	46.80%	85.10%
3.	*Kara-Padayo Suptata Daho*	41.48%	78.72%
4.	*Mukha-Talu-Kantha Shosha*	36.66%	61.90%
5.	*Madhuryam Asyata*	27.64%	67.64%



Graph 1: Result of Treatment Percentage Mean of Subjective Criteria

Table 16: Result of Treatment Percentage Mean of Objective Criteria

S.No	Parameters	Mean Change Treatment %	
		After Treatment	After Follow-up
Objective Parameters			
1.	Fasting Blood Sugar	36.30%	58.46%
2.	Post Prandial Blood Sugar	38.33%	56.66%
3.	Fasting Urine Sugar	37.24%	53.44%
4.	Post Prandial Urine Sugar	36.86%	52.90%
Total Mean %		**38.21%**	**65.61%**

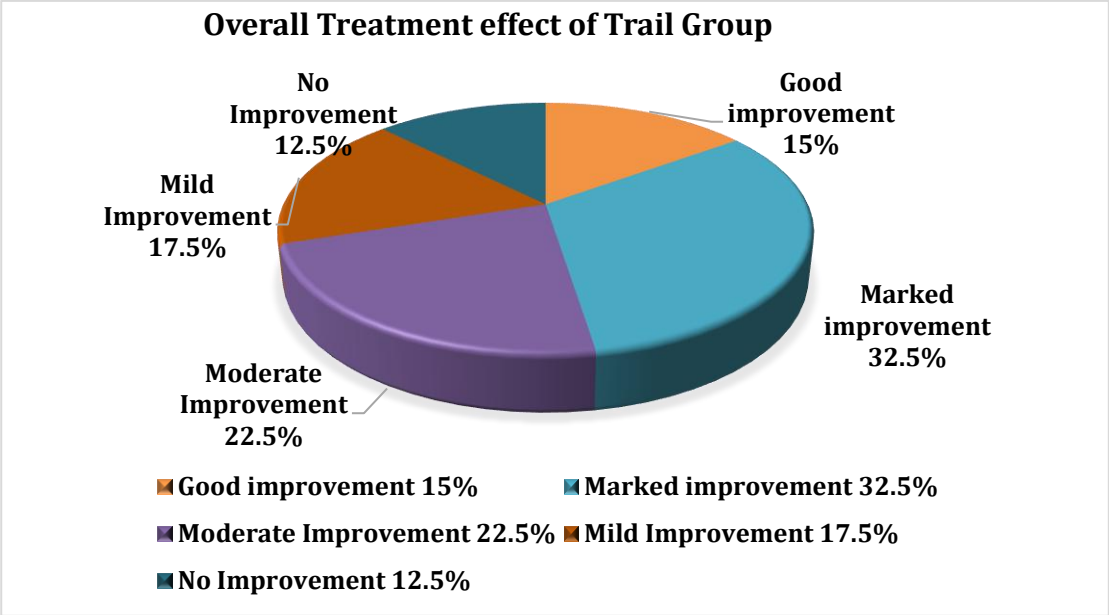


Graph 2: Result of Treatment Percentage Mean of all Criteria

Overall Treatment Result

Table 17: Overall Assessment of Post Treatment Effect in Trail Group

S.No.	Criteria	% Grading	No. of Pt. in Trail Group	% of Results
1.	Good Improvement	91% - 100%	6	15%
2.	Marked Improvement	71% - 90%	13	32.5%
3.	Moderate Improvement	51% - 70%	9	22.5%
4.	Mild Improvement	31% - 50%	7	17.5%
5.	No Improvement	0% - 30%	5	12.5%
Total			40	100%



Graph 3: Overall Assessment of Post Treatment Effect in Trail Group

DISCUSSION

Research discussions, grounded in scriptural wisdom, are essential for validating hypotheses and expanding knowledge. With the rapid rise of industrialization and sedentary lifestyles, health issues like Prameha (Type 2 Diabetes Mellitus) have become increasingly prevalent. Irregular eating habits and lack of physical activity contribute to these conditions, affecting both physical and mental health. A holistic approach, rooted in ancient *Ayurvedic* principles, may provide an effective solution to these modern health challenges.

Discussion on Disease– *Prameha*

Prameha, a complex metabolic disorder described in *Ayurveda*, closely resembles Diabetes Mellitus in both manifestation and symptoms. It is considered a chronic, recurring disease caused by an imbalance of the three *Doshas—Vata, Pitta*, and *Kapha*. *Prameha* involves two primary pathological processes: *Aavaranjanya Prameha*, which is caused by excess intake of heavy, oily, sour, and salty foods that disturb the *Kapha* and *Pitta doshas*, leading to metabolic dysfunction and the excretion of vital components like *Oja* through urine. The second type, *Dhatukshayajanya Prameha*, is due to a lack of nourishment and depletion of essential *Dhatus*, aggravating *Vata* and causing metabolic disturbances.

A key factor in *Prameha* is *Dhatvagni-Mandya*, where weakened *Agni* impairs digestion and leads to the formation of *Ama*. This disrupts the nourishment of tissues, especially *Meda*, and contributes to degeneration. Restoring *Agni* is therefore crucial in the treatment of *Prameha*.

Modern medicine defines Diabetes Mellitus as a group of disorders characterized by chronic hyperglycemia and disturbances in carbohydrate, fat, and protein metabolism due to defects in insulin secretion or action. Type 1 Diabetes involves autoimmune destruction of insulin-producing cells, while Type 2 Diabetes is marked by insulin resistance, often related to obesity and a sedentary lifestyle.

Ayurveda correlates *Prameha* with both forms of Diabetes Mellitus. *Sthoola-Prameha* correlates with Type 2 Diabetes, where excess weight and lifestyle factors contribute to insulin resistance. *Krusha-*

Prameha is akin to Type 1 Diabetes, characterized by a deficiency in insulin production. *Ayurveda* also emphasizes the hereditary component of *Prameha*, similar to the genetic predisposition seen in modern diabetes. Treatment in *Ayurveda* involves *Shodhana* and *Shamana* therapies. *Palasha Beeja Choorna Vati*, known for its *Kapha-Medohara* properties, is used to address metabolic imbalances, balance doshas, and rejuvenate the system, offering a holistic approach to managing metabolic disorders like Diabetes Mellitus

Discussion on Drug

Palasha Beeja Ghana Vati has *Katu, Tikta*, and *Kashaya Rasa*, *Laghu* and *Ruksha Guna, Ushna Veerya*, and *Katu Vipaka*. Its therapeutic actions include *Kapha-Vata Shamaka, Pramehahara, Arshoghna, Krimighna, Gulmahara, Kushtahara*, and *Udara Roganashaka.*

Pharmacognostic Study: The study includes both physical and chemical evaluations to assess quality and efficacy.

i. **Physical Evaluation:** The total ash content of *Palasha Beeja Ghana Vati* is 5.150%, within permissible limits. Loss on Drying is 6.93%, and acid-insoluble ash is 0.291%, with water-insoluble ash at 1.108%, indicating non-digestible material.

ii. **Extractive Value:** Water-soluble extracts are 49.544%, and alcohol-soluble extracts are 13.902%. These suggest the formulation contains both water-soluble and alcohol-soluble bioactive compounds, supporting its therapeutic efficacy. All parameters meet *Ayurvedic* Pharmacopoeia of India (API) standards, confirming the formulation's quality.

Phytochemical Analysis

i. **Qualitative Analysis:** The analysis reveals the presence of carbohydrates, reducing sugars, amino acids, steroids, flavonoids, and saponin glycosides. It also shows the absence of monosaccharides, pentose sugars, non-reducing sugars, hexose sugars, proteins, alkaloids, tannins, cardiac glycosides, and anthraquinone glycosides in water-soluble media. In alcohol-soluble media, carbohydrates, pentose sugars, proteins, amino acids, flavonoids, cardiac glycosides, and saponin glycosides are present, while reducing sugars, monosaccharides, non-reducing sugars, hexose sugars, steroids, alkaloids, tannins, and anthraquinone glycosides are absent. These compounds contribute antioxidant, anti-inflammatory, and antimicrobial effects.

ii. **Total Flavonoid Content:** The cold-water extract of *Palasha Beeja* has 1.41 ± 0.35 mg QE per gram of extract. Flavonoids support detoxification, metabolism, and disease management, enhancing the formulation's therapeutic effects.

iii. **Total Phenolic Content:** The hydro-alcoholic extract (70%) has 9.65 ± 0.32 mg GAE per gram, indicating a high concentration of phenolic compounds with antioxidant properties, which enhance the formulation's therapeutic efficacy.

Foreign Matter: Strict quality control ensures that raw materials are free from contaminants, maintaining the pharmacological effectiveness of *Palasha Beeja Ghana Vati*. Low foreign matter prevents dilution of active ingredients, ensuring compliance with pharmacopoeia standards and enhancing the formulation's safety and efficacy

Overall Effect of Therapy

The therapy's effectiveness was graded as unchanged (0-30%), mild improvement (31-50%), moderate improvement (51-70%), marked improvement (71-90%), and cured (91-100%). In the trial group, 15% showed good improvement, 32.5% marked improvement, 22.5% moderate improvement, 17.5% mild improvement, and 12.5% showed no improvement, with most experiencing some benefit.

CONCLUSION

The study highlights the significant therapeutic efficacy of *Palasha Beeja Ghana Vati* in managing *Prameha* (Type 2 Diabetes Mellitus). *Prameha* is a *Tridosha Vyadhi*, predominantly involving *Kapha* and *Vata Doshas*.

This condition, especially *Santarpanajanya* and *Aavaranajanya Prameha*, aligns closely with Type 2 Diabetes Mellitus. Common symptoms observed in patients included the classical triad of polyuria, polydipsia, and polyphagia, while some cases exhibited elevated blood sugar without typical symptoms, as described in *Charaka Samhita*.

The study involved 40 patients who were administered *Palasha Beeja Ghana Vati* (500 mg twice daily) for 30 days, followed by a 15-day follow-up. Demographic analysis revealed that most participants were married (95%) and male (60%), belonging to the age group of 46–52 years (35%). A significant portion were middle class (27.5%), residing in rural areas (70%), following the Hindu religion (80%), and engaged in business-class occupations (35%) with sedentary work habits (45%). Additionally, 42.5% had a tea-drinking habit. The majority had *Kapha-Vata Prakruti* (65%), *Mrudu* and *Madhyama Koshta* (40% each), *Vishamagni* (45%), a chronicity of 2.1–4 years (22.5%), and 60% reported *Diwaswapna*. No adverse effects were observed during the study.

Statistical Outcomes

Treatment results were statistically significant (*p<0.001*) across all parameters. Subjective improvements included 75.68% relief in *Prabhuta Avila Mutrata*, 85.10% in *Trushna*, 78.72% in *Kara-Padayo Suptata Daho*, 61.90% in *Mukha-Talu-Kantha Shosha*, and 67.64% in *Madhuryam Asyata* after follow-up. Objective improvements included 58.46% relief in fasting blood sugar, 56.66% in postprandial blood sugar, 53.44% in fasting urine sugar, and 52.90% in postprandial urine sugar after follow-up.

Research Implications

The treatment exhibited a 38.21% overall improvement after treatment (BT-AT) and 65.61% improvement after follow-up (BT-AF). These results affirm that *Palasha Beeja Ghana Vati* effectively reduces symptoms and improves glycemic control in *Prameha*. The study underscores its potential as a safe and effective *Shamana Chikitsa* in diabetes management, with no adverse effects observed. Further research with larger sample sizes and extended durations is recommended to substantiate these findings.

Hypothesis Acceptance: Based on the observations and results, the following alternate hypotheses are accepted – There is Significant Effect of *Palasha Beeja Ghana Vati* (Butea monosperma Lan-Kutze) in *Prameha* W.S.R. to Diabetes Mellitus-II.

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***Address for correspondence**
Dr. Anuj Jain
Post Graduate Scholar,
Dept. of Dravya Guna,
Sri Shivayogeeshwar Rural Ayurvedic Medical College and Hospital, Inchal, Belagavi, Karnataka, India.
Email: anujayurved@gmail.com

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